Guidelines for Prescribing Controlled Substances

The Kentucky Board of Medical Licensure, in cooperation with the KMA Ad Hoc Committee to Study Guidelines for Prescribing Controlled Substances, has developed the following guidelines.

These guidelines were formulated from various sources and literature. They are offered to assist physicians in safe and appropriate decision making in prescribing controlled substances.

I. **Diagnosis.** Establish a working diagnosis based on an adequate history, physical examination, and appropriate diagnostic tests.

II. **Management Plan.** Formulate and document a plan of treatment. Make appropriate referrals if needed for optimum diagnosis and management.

III. **Eliminate Alternatives.** Before beginning a regimen of controlled drugs, document that other measures and drugs have been inadequate or not tolerated.

IV. **Be Aware of Drug Seekers.** Learn drug seeking behaviors and obtain personal and family histories of chemical dependency.

V. **Informed Consent.** Document that patient has acknowledged that he/she has been advised of the risks of the proposed treatment. Family conferences may be helpful to establish ground rules.

VI. **Monitoring.** Maintain regular monitoring of the patient and his progress. Consider “drug holidays” to monitor compliance and continued need.

VII. **Control.** Make sure that you are in control of the drug supply. Keep detailed records. Assure that one physician orders the medications and one pharmacy fills all prescriptions. In most cases require the patient to return for refill authorization.

VIII. **No Self-prescribing**. Physicians should studiously avoid prescribing to self, immediate family, or staff.

IX. **Anorectic Drugs.** Avoid the use of Schedule III and IV anorectic drugs.

X. **Muscle Relaxants.** Prescribe muscle relaxants with caution on a chronic basis, particularly those with known addictive potential. Examples include, but are not limited to, carisoprodol (Soma) and diazepam (Valium).

XI. **Anxiolytic Drugs.** Use as much caution with addictive anxiolytic drugs as with opioid drugs.

XII. **Common Problems.** Be aware of common problems faced by physicians who come under investigation:

(1) Inadequate records/documentation.
(2) Failure to document diagnosis (pain is a symptom, not a diagnosis)
(3) Prescribing controlled substances without a trial of alternative treatments.
(4) Failure to monitor side effects of drugs, and
(5) Failure to document rational reason for chronic use of controlled substance.

A. General Guidelines. These are simple, general recommendations for the safe and proper use of prescription drugs with abuse potential. [5]
"It's not important what you prescribe but how well you manage the patient's care and create a record of that care"

I. **Diagnosis.** First and foremost before prescribing anything, establish a diagnosis which is supported by adequate history and physical examination and the results of appropriate diagnostic tests. Unfortunately it is often found that a symptom, rather that a diagnosis, is the basis for a given treatment.

II. **Management Plan.** Formulate a treatment plan that includes appropriate non-addictive modalities. Make referrals to appropriate specialists, if necessary, to establish the diagnosis and insure that alternative treatment modalities are tried. Include all correspondence and test results in the patient's chart. One such management plan[1] follows:
   1. Determine if patient has had an adequate trial of a non-drug regimen of treatment (exercise, physical therapy, behavior modification, etc) and if not, initiate such a regimen.
   2. Prescribe non-narcotic analgesics, such as NSAIDs, acetaminophen, Midrin, non-habituating muscle relaxants, or Ultram (if still listed as a nonscheduled agent).
   3. Prescribe weak opioids (propoxyphene, Talwin, codeine, oxycodone).
   4. Prescribe stronger opioids (morphine, Demerol, Dilaudid, etc).
   5. Combinations of any of the above may be indicated, even from the beginning.

III. **Eliminate Alternatives.** Before beginning a regimen of controlled drugs, make a determination through actual clinical trial or through patient records and history that non-addictive regimens have been inadequate or are unacceptable by comparison, e.g., intolerance or allergy to nonsteroidal anti-inflammatory drugs. The assertion by a patient that a certain narcotic, e.g., Percodan, works well for him/her is not an adequate history of failure of other methods or drugs. Too often physicians who have come under review have instituted treatment with potent opioids apparently without ever considering other forms of treatment. "How much is too much?" is a question often asked. No agency will be able to answer that question specifically. Validity of treatment must be established case by case and by the quality and content of the diagnostic and therapeutic regiments implemented.

IV. **Be Aware of Drug Seekers.** Make sure you are not dealing with a drug seeking patient. If the patient is new or otherwise unknown to you, obtain, at a minimum, an oral drug history, and discuss chemical use and family chemical history with the patient. If you have any doubts, you may consider obtaining a chemical dependency evaluation prior to prescribing a potentially addictive substance.

V. **Informed Consent.** Before prescribing a potentially addictive drug, assure that the patient has an understanding of the relative risks and

benefits of the drug, based on relevant published literature, e.g., PDR, AMA Drug Evaluations, USP DI. It may be beneficial to obtain written informed consent in selected patients. When the possibility of long term use of potentially addictive substances exists, it may be helpful to educate the family to the risks and benefits of the medication. One effective mechanism to accomplish this may be holding a family conference. The refusal of a patient to permit a family conference may be a red flag alerting the physician to potential addictive tendency.

VI. **Monitoring.** Maintain regular monitoring of the patient, including regular and frequent updating of the history and physical evaluation. Adequate monitoring may include:

1. History update
   a. Assessment of compliance
      (1) Are medications being taken as prescribed?
      (2) Is patient adhering to/cooperating with alternative non-addicting modalities?
      (3) Record compliance with time frame (asking for refills before time, "losing" doses of prescriptions, trying to use other physicians or pharmacies).
      (4) Record when told to return and when refills may be made.
   b. Document patient's response to treatment (improved? worse?)
   c. Document alterations or addictions to the management plan.

2. Physical update
   a. Vital signs, particularly weight in patients receiving anorectics or narcotics.
   b. General appearance (does habitus suggest pain, anxiety, depression?).
   c. Specific signs – pertinent to the individual patient, e.g., improved or decreased range of motion.

VII. **Control.** Make sure that you are in control of the drug supply. To do this, at a minimum keep detailed records of the type, dose, and amount of the drug prescribed**. You** must monitor, record, and control all refills. One way to accomplish this is to require the patient to return to obtain prescriptions. Routine call-in of prescription drugs is to be avoided. The physician should keep a chronological drug log of controlled substances, e.g., a flow sheet. Communicate with other treating physicians and the patient's pharmacist. The patient should use one physician and one pharmacy for his/her controlled substance prescriptions. If either changes, the other should be notified.[1]

VIII. **Self-prescribing**. Physicians should avoid prescription of any controlled substance or any drug with addictive potential to self, immediate family, or staff. No prohibitive laws to that effect exist, as far as the committee is

aware. However the recommendation is offered to prevent any appearance of impropriety.[8]

IX. **Anorectic Drugs**. Avoid the use of Schedule III And IV anorectic drugs. If the mechanism is in place to adequately assess, monitor, and control the short term use of anorectics and physicians wish to enter that therapeutic arena, then the following criteria should be followed.[2]

1. Prior to initially prescribing any Schedule III or IV anorectic:
   (a) Obtain a thorough medical and weight loss or gain history;
   (b) Perform a complete physical examination;
   (c) Determine that the patient is a medically obese adult;
   (d) Require the patient to make a substantial good faith effort at weight reduction, under the physician's supervision, without utilizing drugs;
   (e) Provide the patient with a carefully prescribed diet, together with counseling on exercise, nutrition, and other appropriate supportive therapy.
2. To appropriately prescribe anorectics the physician should:
   (a) Ask the patient whether he/she has currently or previously obtained or used anorectics from one or more practitioners, and record the answer.
   (b) Ascertain whether the patient has a history or potential of abuse of drugs, including alcohol.
   (c) Rule out conditions contradicting the use of anorectics, including but not limited to pregnancy, hypertension, or hypersensitivity or idiosyncrasy to the drugs.
   (d) Advise the patient of the drug's potential for abuse, and the possibility of leading to dependence.
   (e) Consider the possibility that the patient will obtain the drug for a nontherapeutic use or distribution to others, and that there is an illicit market for such drugs.
3. A physician should not normally prescribe a Schedule III or IV anorectic drug to any patient:
   (a) In a daily dosage greater than the maximum FDA approved dosage recommendation; or
   (b) For an aggregate period in excess of 120 days during any 12 month period.
4. A physician should not institute or continue the prescription of Schedule III or IV anorectic drugs if:
   (a) The patient is not a proper candidate for the use of anorectics;
   (b) The patient has developed tolerance to the appetite suppressant effect of the drug or has experienced euphoria followed by irritability or depression; or
   (c) The patient has engaged in excessive use, misuse, or abuse of the anorectic, or has otherwise consumed or disposed of the drug(s)

other than in strict compliance with the directions and indications for use given by the physician.

It should be noted that lay literature has been disseminating misinformation about certain anorectics. Touting them as "new" and not having abuse problems, phentermine and fenfluramine have been presented to the public by various publications. Standard pharmacy and medical reference works[3,4] identify them along with the rest of the following as having marked abuse potential:

Amphetamines and their derivatives
Dextroamphetamine and d. sulfate (Dexedrine, Biphetamine) **Cii**
Phendimetrazine (Bontril et al) **Ciii**
Mazindol (Sanorex) **Civ**
Fenfluramine (Pondimin) **Civ**
Phentermine (Fastin, lonamin, Adipex) **Civ**
Benzphetamine (Didrex) **Ciii**
Methylphenidate (Ritalin) **Cii**

(This list is for your convenience; it is not presented as all-inclusive).

X. **Muscle Relaxants**. Certain muscle relaxants should be prescribed with the same caution as opioids and other controlled substances. Carisoprodol (Soma) is metabolized to meprobamate, which is known to be addictive. Diazepam (Valium), sometimes used as a muscle relaxant, also has addictive potential.

XI. **Anxiolytic Drugs**. Controlled anxiolytic drugs (benzodiazepines in particular) should be used with as much caution as opioid drugs. The same common sense guidelines listed elsewhere should be followed. Functional status and quality of life issues should be examined. Avoid treating subjective complaints. The quality of the initial evaluation, documented follow-up visits, consultations, and alternative treatment and medications, are more important than the absolute amount of the medication given.

XII. **Common Problems**. Problems faced by physicians when coming under review and investigation by the Board of Licensure and other entities, such as governmental agencies or civil litigation, include:

(1) Inadequate records/documentation.
(2) Failure to establish a diagnosis. Subjective complaint of pain is not a diagnosis, it is a symptom.
(3) Utilizing controlled substances in treatment without alternative methods having been explored and exhausted.
(4) Failure to monitor the side effects of a drug, e.g., monitoring for potential indicators of drug addiction.
(5) Failure to document why the continued use of controlled substance(s) is necessary.

References

1. Kennedy L.D. Personal communication.
2. Guidelines for prescribing amphetamine, amphetamine-like and anorectic controlled substances (schedule III and IV). Kentucky Board of Medical Licensure Newsletter. Spring 1994
3. Physicians Desk Reference. Medical Economics Co. Montvale, NJ. 1996
4. DI for Providers. US Pharmacopeial Convention. Silver Springs, MD. 1995
5. Management of prescribing. Minnesota Board of Medical Examiners Update. Fall 1990. 1-5
6. Portnoy RK. Pharmacologic management of chronic pain. In: Fields H, ed. *Pain Syndromes in Neurology*. Butterworth Heinemann Publisher; CH 11.
7. Fields H, Liebeskind E, eds. Opioid therapy for chronic nonmalignant pain: current status. In*: Pharmacological Approaches to the Treatment of Chronic Pain: New Concepts and Critical Issues, International Association for the Study of Pain: Progress in Pain Research and Management*. JASP Press; 1994: Vol 1. CH 16, pp 247-287.
8. Self-prescribing and prescribing to immediate family members. Kentucky Board of Medical Licensure Newsletter. Fall 1991.
9. Elements of a good medical record. Kentucky Board of Medical Licensure Newsletter. September 1992.
10. Guidelines on physical examinations by physicians, adopted by the Kentucky Board of Medical Licensure. Kentucky Board of Medical Licensure Newsletter. March 15, 1990.
11. Portnoy R, ed. Special section on pain and addiction. *J Pain & Symptom Management*. 8:5 253-305. July 1993.
12. Portnoy R, ed. Adjunctive analgesics in pain management: part II. *J Pain & Symptom Management*. 9:7 423-453. Oct 1994.

Adopted: June 20, 1996